



## General

#### Guideline Title

Addressing viral hepatitis in people with substance use disorders.

## Bibliographic Source(s)

Substance Abuse and Mental Health Services Administration. Addressing viral hepatitis in people with substance use disorders. HHS publication no. (SMA) 11-4656. Rockville (MD): Substance Abuse and Mental Health Services Administration; 2011. 132 p. (Treatment improvement protocol (TIP) series; no. 53).

#### Guideline Status

This is the current release of the guideline.

## Recommendations

## Major Recommendations

Note from the National Guideline Clearinghouse (NGC): The following information is taken from the section summaries. For a full discussion of the guidance and rationale, please see the original guideline document.

Screening for Viral Hepatitis

Screening for hepatitis A involves a blood test that detects antibodies produced by a person's immune system to fight the virus.

- A positive test result means the person is currently infected, had been infected, or has been vaccinated against infection and is immune to infection
- A negative test result means the person has never been infected or vaccinated. This person should probably be vaccinated against hepatitis
  A virus (HAV).

Screening for hepatitis B involves blood tests that measure hepatitis B virus (HBV) antigens and antibodies.

- The test for hepatitis B surface antigen detects the presence of HBV. A positive result means the person is currently infected and can pass the infection to others. If, after 6 months, the person still tests positive, his or her HBV infection is considered chronic.
- The test for hepatitis B core antibody detects the presence of the core protein of the virus. A positive result means the person has been
  infected with HBV, but it does not specify whether the person has cleared the virus, still has the infection, or is immune to reinfection. A
  negative result means the person has never been infected with HBV. This test does not tell whether a person is immune to infection or
  reinfection.
- The test for hepatitis B surface antibody detects the presence of the surface protein (or the surface antigen) of the virus that appears after the

virus has been cleared (or the person has been successfully vaccinated). People who have surface antibodies have lifetime protection from future HBV infection. In people who do not clear the virus but develop chronic infection, these antibodies never appear.

Screening for hepatitis C involves a blood test to detect antibodies, but the results are not clear cut and should be interpreted carefully.

- A positive test result means the person has been infected with hepatitis C virus (HCV) and might be chronically infected; it does not always mean the person is still infected. Diagnostic tests are needed.
- A negative test result means either the person has not been infected or the person was infected recently and antibodies have not yet appeared. Another test might be needed in 6 months.

Counselors can use the screening as an opportunity to:

- Educate clients about hepatitis
- Identify patterns of risky behavior
- Urge clients to get vaccinated against HAV and HBV
- Educate clients to prevent hepatitis transmission

Evaluation of Chronic Hepatitis

A hepatitis evaluation provides information for making informed decisions about antiviral treatment.

HCV evaluation can include the following:

- Liver panel
- Viral load tests
- Genotype test
- Liver biopsy

Counselors can help clients cope with an evaluation of chronic hepatitis by:

- Helping them identify and weigh the risks and benefits of evaluation
- Exploring the client's feelings
- Helping clients plan how they will cope with waiting for and receiving evaluation results

Helping Clients Make Medical Decisions About Hepatitis Treatment

In determining eligibility for treatment of viral hepatitis, medical care providers consider:

- Timing of hepatitis treatment
- Treatment contraindications
- The presence of more urgent problems
- The likelihood of patients' adhering to hepatitis treatment
- The likelihood of treatment success

Medical care providers, clients, and counselors should work together to consider the advisability of antiviral treatment.

There is growing consensus that people who have injected or still inject drugs can be successfully treated for hepatitis.

Steps to help clients decide whether to begin antiviral treatment include:

- Helping clients understand the meaning of evaluation results for hepatitis treatment
- Assessing clients' substance use disorder (SUD) recovery, mental health issues, support systems, and life circumstances.
- Educating clients about their choices
- Helping clients reframe goals of recovery to include a meaningful, healthy life

Once a client makes a decision about hepatitis treatment, the counselor should support that decision and offer to reconsider in the future if circumstances change.

Clients from special populations might require additional education or advocacy. Their unique needs must be considered in antiviral treatment planning.

#### Hepatitis Treatment

- Hepatitis A rarely requires treatment.
- Chronic HBV can be treated with several oral antivirals; currently, tenofovir or entecavir are the recommended first-line options for initial
  oral treatment.
- Hepatitis C can be treated effectively if discovered early (i.e., in its acute phase), but it is rarely discovered early.
- Treatment for chronic hepatitis C is lengthy, can cause side effects that are difficult to manage in some people, and requires good adherence. It is not appropriate for everyone.
- Some clients might elect (or be advised) to defer antiviral treatment.
- For some people, a liver transplant is the only option. Counselors can help clients through the process.
- Clients in opioid treatment programs (OTPs) are eligible for antiviral treatment.
- Clients who use substances or relapse can achieve a sustained virologic response (SVR) comparable with that of other groups if they adhere to hepatitis treatment.
- HCV/human immunodeficiency virus (HIV) co-infection can be very serious.
- Clients with co-occurring behavioral health disorders can adhere to—and respond to—antiviral treatment.

#### Counseling Approaches for People Who Have Viral Hepatitis

Counselors are in a unique position to provide education, emotional support, and tangible help for clients who have hepatitis.

To be effective, counselors must first be well educated about hepatitis.

#### Key counselor goals should include:

- Ensuring the safety of clients
- Providing reliable information to clients and their families
- Building the therapeutic relationship with clients
- Helping clients understand their diagnoses
- Incorporating client needs in substance abuse treatment planning
- Developing a prevention plan
- Using motivational interviewing
- Confronting the social ramifications of hepatitis
- Addressing relapse issues
- Building support
- · Providing case management

#### Counselors also can help by:

- · Being flexible about treatment logistics (e.g., participation, treatment duration), within accreditation and licensing guidelines
- Being alert to co-occurring mental disorders, particularly depression
- Assessing clients' readiness and using motivational approaches to help clients make medical treatment decisions
- Assessing and mobilizing clients' strengths

#### Counselors can help clients develop social support systems by:

- Providing onsite support groups
- Helping clients locate community-based support groups
- Facilitating onsite peer counseling and support programs
- Facilitating family support through education and counseling

#### Counselors can provide effective, targeted case management, such as:

- Helping clients understand and complete written documents and consent forms
- Helping clients obtain medical care and adhere to medical regimens
- Helping clients find sources for financing medical treatment and medications for hepatitis

#### Adding or Improving Hepatitis Services: A Guide for Administrators

Administrators can add a variety of viral hepatitis services to their programs, such as:

- Hepatitis screening, evaluation, and diagnosis
- Hepatitis prevention activities, including education and vaccination
- · Hepatitis treatment or referral to vetted medical care providers for treatment
- Support services for clients needing hepatitis treatment
- Outreach to at-risk groups

#### Successful programs tend to have:

- At least one administrator to promote efforts to incorporate hepatitis services into the treatment program
- At least one change agent on staff who advocated for the services
- Collective buy-in from the treatment team

#### Administrators should be familiar with:

- · Confidentiality and privacy issues
- · Legal requirements for informed consent
- Staff member rights pertaining to risks of hepatitis exposure

## Clinical Algorithm(s)

An algorithm for the hepatitis C virus (HCV) screening process is provided in the original guideline document.

## Scope

## Disease/Condition(s)

Substance use disorder (SUDs)

## Other Disease/Condition(s) Addressed

- Hepatitis A virus (HAV)
- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)

## Guideline Category

Counseling	
Diagnosis	

Management

Evaluation

Prevention

Screening

Treatment

## Clinical Specialty

Family Practice

Internal Medicine
Psychiatry
Psychology
T , 1 1 T T
Intended Users
Advanced Practice Nurses
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Public Health Departments
Social Workers
Substance Use Disorders Treatment Providers
Guideline Objective(s)
To improve care for clients with SUDs by increasing knowledge of viral hepatitis among staff in behavioral health programs that provide substance abuse treatment
Target Population
Individuals in the United States with substance use disorders who are diagnosed with or are at risk of viral hepatitis

Interventions and Practices Considered

Screening/Diagnosis/Evaluation

1. Laboratory tests

Infectious Diseases

- Hepatitis A antibodies; hepatitis B surface antigen, core antibody, or surface antibody; hepatitis C antibodies
- Liver panel
- Viral load
- Viral genotype
- Liver biopsy
- 2. Interpretation of results
- 3. Frequency of testing
- 4. Risk assessment
- 5. Assessment of comorbid conditions and contraindications to treatment

#### Counseling/Prevention

- 1. Patient education on disease, treatments, and prevention of transmission
- 2. Vaccination of patients for hepatitis A virus (HAV) and hepatitis B virus (HBV)
- 3. Counselor support of decision to treat or not treat
- 4. Provision of tangible help
- 5. Development of social support systems
- 6. Setting counselor and patient goals
- 7. Administrator familiarity with legal and ethical issues

#### Management/Treatment

- 1. Timing of hepatitis treatment
- 2. Oral antiretroviral therapy (e.g., tenofovir or entecavir) for hepatitis B
- 3. Prolonged therapy for hepatitis C
- 4. Management of treatment side effects
- 5. Liver transplantation
- 6. Provision of case management

## Major Outcomes Considered

- · Accuracy of screening tests
- Treatment success rate (sustained virologic response)
- · Effect of education and diagnosis on risky behavior
- Adherence to treatment
- Adverse effects of treatment
- Risk of reinfection
- Relapse rate

## Methodology

#### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

The series of comprehensive searches undertaken for this literature review was done by the University of Maryland's Center for Substance Abuse Research (CESAR), starting in February 2007. The searches covered literature published in English from January 1999 through July 2009. All fields (including title, abstract, and key terms) were searched.

The initial search, done through the PubMed database of clinical and nursing journals and through the Cochrane Review, aimed to identify review articles, including meta-analyses, practice guidelines, reviews of the literature, and evaluation studies. The initial search, conducted by a professional librarian from CESAR, used the following terms:

- PubMed: Hepatitis, viral human [main heading] AND substance-related disorders [main heading] AND limits (reviews, meta-analyses, practice guidelines, evaluation studies). The initial search and two updates were done between February 1, 2007, and May 26, 2009.
- Cochrane Review: Hepatitis and selected relevant citations.

This search elicited very few documents. Therefore, the scope of the search was broadened to include overview articles on the management of

hepatitis in people who have a history of substance use disorders. A followup search of the literature was conducted in July 2007 and again in May 2009. These searches used the following terms:

- PubMed: (hepatitis, viral human [main heading] OR hepatitis, chronic [main heading] OR hepatitis, toxic [main heading]) AND (substance-related disorders [main heading]) OR substance abuse treatment centers [main heading]) AND date limits.
- CINAHL (Cumulative Index to Nursing & Allied Health Literature), PsycINFO, SocINDEX, and Academic Search Premier:
  - (viral hepatitis OR hepatitis C) [all text fields] AND (substance abuse OR drug abuse) [all text fields] AND reviews [text word] AND date limits
  - (viral hepatitis OR hepatitis C) [all text fields] AND (substance abuse OR drug abuse) [all text fields] AND (NOT reviews) AND, for PsycINFO only, (Drug and Alcohol Rehabilitation [classification 3383]).

Supplemental searches were undertaken on specific targeted topics, such as the use of directly observed antiviral therapy among people in drug treatment settings. These supplemental searches were conducted in August 2007 and updated on May 26, 2009. (Refer to the Appendix of the literature review companion document [see the "Availability of Companion Documents" field] for detailed information on supplemental search terms.)

Using the search strategy developed for the initial and followup literature searches, the literature review was updated in May 2009, January 2010, March 2011, and August 2011.

Treatment improvement protocol (TIP) writers reviewed abstracts for citations found. They eliminated citations that focused on preclinical research or on the specific medical treatment of hepatitis. They also excluded studies that did not clearly differentiate between hepatitis patients with a history of drug use and those without this history.

After references were selected using these search procedures, the bibliographies or citation lists from these references were reviewed to find older, seminal literature appropriate to this topic. Members of the TIP consensus panel suggested additional research that would be relevant to the TIP.

Although cultural differences in healthcare systems, approaches to substance use disorder (SUD) treatment, prejudice faced by people who have hepatitis and SUDs, and many other factors make drawing comparisons across national boundaries difficult, foreign studies written in English are included to supplement the scant research on the topic that has been conducted in the United States. Where data from only the United States are relevant, or where the research is proportionate to that in other countries and does not differ in its conclusions, the literature review (see the "Availability of Companion Documents" field) cites only U.S. data; in other cases, the country where the research was conducted is identified.

#### Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

**Expert Consensus** 

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

#### Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Treatment Improvement Protocol (TIP) Development Process

TIP topics are based on the current needs of behavioral health professionals and other healthcare providers for information and guidance. After selecting a topic, Substance Abuse and Mental Health Services Administration (SAMHSA) invites staff members from Federal agencies and national organizations to be members of a resource panel that reviews an initial draft prospectus and outline and recommends specific areas of focus, as well as resources that should be considered in developing the content for the TIP. These recommendations are communicated to a consensus panel composed of experts on the topic who have been nominated by their peers. In partnership with Knowledge Application Program writers, consensus panel members participate in creating a draft document and then meet to review and discuss the draft. The information and recommendations on which they reach consensus form the foundation of the TIP. A panel chair ensures that the guidelines mirror the results of the group's collaboration.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

Published cost analyses were reviewed (see the literature review in the "Availability of Companion Documents" field).

#### Method of Guideline Validation

External Peer Review

## Description of Method of Guideline Validation

A diverse group of experts closely reviews the draft document. Once the changes recommended by these field reviewers have been incorporated, the treatment improvement protocol (TIP) is prepared for publication, in print and online.

## Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

## Benefits/Harms of Implementing the Guideline Recommendations

#### **Potential Benefits**

Appropriate screening, evaluation, and treatment of people with substance use disorders and viral hepatitis

#### Potential Harms

- · Liver biopsies have risks, including pain and internal bleeding.
- Side effects of medications (see Exhibit 5-1 of the original guideline document for detailed information on side effects of medication for chronic hepatitis B.)
- Drug interactions (see Exhibit F-1 in Appendix F of the original guideline document for information on potential interactions among medications used to treat chronic hepatitis and behavioral health conditions.)

## Contraindications

#### Contraindications

- Contraindications to receiving the hepatitis A vaccine include having a severe allergy to vaccine components and being moderately or
  severely ill at the time the vaccination is offered. All clients, especially pregnant women, should consult their medical care provider to
  determine whether they should get vaccinated against hepatitis A.
- Contraindications to getting the hepatitis B vaccine include having had a severe allergic reaction to a previous dose or to a component of the vaccine. Clients should discuss the vaccination with a medical care provider.
- Contraindications to hepatitis treatment include:
  - Major uncontrolled psychiatric disorders (e.g., depression, bipolar, schizophrenia)
  - Prior solid organ (i.e., renal, heart, lung) transplantation
  - Pregnancy or unwillingness to use adequate contraception
  - A condition that would make hepatitis treatment dangerous (e.g., severe uncontrolled hypertension, untreated heart failure, significant
    and uncontrolled coronary heart disease, poorly controlled diabetes, chronic pulmonary disease)
  - An allergy or hypersensitivity to medications (e.g., interferon, ribavirin)

#### Pregnancy and Antiviral Treatment

- Interferon and ribavirin can cause birth defects, so pregnant women (or their sexual partners) should not be administered these medications. Women who are breastfeeding should not undergo antiviral treatment for hepatitis.
- A man receiving antiviral treatment for hepatitis C virus (HCV) should not impregnate a woman during his treatment and for 6 months thereafter because of the possible risk of birth defects.
- Women with HCV have to decide whether to complete antiviral treatment before trying to become pregnant or to delay treatment until after delivery.

## **Qualifying Statements**

## **Qualifying Statements**

- The views, opinions, and content of this publication are those of the authors and do not necessarily reflect the views, opinions, or policies of Substance Abuse and Mental Health Services Administration (SAMHSA) or U.S. Department of Health and Human Services (HHS).
- Although each consensus-based Treatment Improvement Protocol (TIP) strives to include an evidence base for the practices it
  recommends, SAMHSA recognizes that behavioral health is continually evolving, and research frequently lags behind the innovations
  pioneered in the field. A major goal of each TIP is to convey "front-line" information quickly but responsibly. If research supports a
  particular approach, citations are provided.

## Implementation of the Guideline

## Description of Implementation Strategy

An implementation strategy was not provided.

## Implementation Tools

Clinical Algorithm

Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

#### **IOM Care Need**

Getting Better

Living with Illness

Staying Healthy

#### **IOM Domain**

Effectiveness

Patient-centeredness

## Identifying Information and Availability

## Bibliographic Source(s)

Substance Abuse and Mental Health Services Administration. Addressing viral hepatitis in people with substance use disorders. HHS publication no. (SMA) 11-4656. Rockville (MD): Substance Abuse and Mental Health Services Administration; 2011. 132 p. (Treatment improvement protocol (TIP) series; no. 53).

## Adaptation

Not applicable: The guideline was not adapted from another source.

#### Date Released

2011

## Guideline Developer(s)

Substance Abuse and Mental Health Services Administration (U.S.) - Federal Government Agency [U.S.]

## Source(s) of Funding

United States Government

#### Guideline Committee

Consensus Panel

## Composition of Group That Authored the Guideline

Panel Members: David A. Fiellin, M.D. (Chair), Professor of Medicine and of Public Health and Associate Professor of Investigative Medicine, Yale University School of Medicine, New Haven, Connecticut; Valentin Bonilla, Jr., RPA, Chief Physician Assistant, Methadone Maintenance Medical Center, Beth Israel Medical Center, New York, New York; Danielle Brown, M.P.H., Clinical Research Supervisor, Mt. Sinai Medical Center, Mount Vernon, New York; Bruce Burkett, Executive Director, Missouri Hepatitis C Alliance, Columbia, Missouri; Eugenia Curet, M.S.W., Ph.D., Clinical Instructor in Public Health, Administrative Director, Adult and Adolescent Services Clinics, Cornell Weill Medical College, New York, New York; Brian R. Edlin, M.D., Associate Professor of Medicine and Public Health, Center for the Study of Hepatitis C, Cornell Weill Medical College, New York, New York; William James Harrison III, M.H.S., CADC, Site Director, Brandywine Counseling, Inc., Wilmington, Delaware; Alain Litwin, M.D., M.P.H., Division of Internal Medicine, Montefiore Medical Center, Bronx, New York; Susan Simon, President and Founder, Hepatitis C Association, Scotch Plains, New Jersey; Shiela M. Strauss, Ph.D., Associate Professor, Director, Muriel and Virginia Pless Center for Nursing Research, New York University College of Nursing, New York, New York; Theodore Paul Ziegler, Chief Executive Officer, Community Health Center, Akron, Ohio

President and Founder, Hepatitis C Association, Scotch Plains, New Jersey; Shiela M. Strauss, Ph.D., Associate Professor, Director, Muriel and Virginia Pless Center for Nursing Research, New York University College of Nursing, New York, New York; Theodore Paul Ziegler, Chief Executive Officer, Community Health Center, Akron, Ohio
Financial Disclosures/Conflicts of Interest
Not stated
Guideline Status
This is the current release of the guideline.
Guideline Availability
Electronic copies: Available in Portable Document Format (PDF) from the Substance Abuse and Mental Health Services Administration (SAMHSA) Web site
Availability of Companion Documents
The following is available:
<ul> <li>Addressing viral hepatitis in people with substance use disorders. A review of the literature. Rockville (MD): Substance Abuse and Mental Health Services Administration; 2011. 50 p. Electronic copies: Available in Portable Document Format (PDF) from the Substance Abuse and Mental Health Services Administration (SAHMSA) Web site</li> </ul>
In addition, a sample policy for screening for hepatitis is available in the original guideline document.
Patient Resources

None available

#### **NGC Status**

This NGC summary was completed by ECRI Institute on August 21, 2012. The information was verified by the guideline developer on August 30, 2012.

## Copyright Statement

No copyright restrictions apply.

## Disclaimer

#### NGC Disclaimer

The National Guideline Clearinghouseâ, & (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.